

**REMARKS/ARGUMENTS**

The preceding amendments and following remarks are submitted in response to the non-final Office Action mailed December 14, 2004. With this Amendment, independent claims 20 and 35 have been amended. Claims 20-62 remain pending in the Application. Reconsideration, examination and allowance of all pending claims are respectfully requested.

**Objections to the Specification**

In paragraph 2 of the Office Action, the Examiner objected to the specification, stating that the phrase "now is U.S. Patent No. 6,652,448 B2" should be inserted before the phrase "which" on page 1, line 4; and the phrase "now is U.S. Patent No. 6,183,413 B1" should be inserted after the phrase "1998" on page 1, line 5. The Examiner states that appropriate correction is required.

In response thereto, Applicant has amended the specification to include reference to the above-referenced patent applications. Applicant asserts that this amendment overcomes the Examiner's objection to the specification.

**35 U.S.C. § 102 Rejections**

In paragraph 4 of the Office Action, the Examiner rejected claims 20-25, 29-33, 35, 38-40, and 44-47 under 35 U.S.C. § 102(b) as being anticipated by *Isaacson* (U.S. Patent No. 3,812,841).

In response to this rejection, Applicant has amended independent claims 20 and 35 to each recite that the stopper includes a plunger portion configured to move longitudinally within the first lumen portion in response to fluidic pressure without allowing fluid to flow through the valve lumen. Antecedent support for these

amendments can be found on page 6, line 17 to page 7, line 2 of the Application, which describes how the plunger portion (34) of the stopper (30) can move between a first position (Figure 1) and a second position (Figure 2) within the first lumen portion (22) without allowing fluid to flow through the valve lumen (14). In use, the ability of the stopper (30) to move longitudinally within the first lumen portion (22) without allowing fluid to flow through the valve lumen (14) permits the valve (10) to open only in response to a sustained pressure exerted by the patient (e.g. by performing a Valsalva maneuver), thereby preventing incidental fluctuations in pressure from opening the valve 10.

Unlike the valve recited in amended claims 20 and 35, the urethra magnetic valve of *Isaacson* does not include a stopper having a plunger portion configured to move longitudinally within a first lumen portion of an elongated housing in response to fluidic pressure without allowing fluid to flow through the valve lumen. In *Isaacson*, a valve member (15) having a spherical or conical shaped configuration is operatively coupled to a magnetic core member (22), which can be externally magnetized via a number of magnetic actuating devices (40,41) to open and close the valve (10). As can be clearly seen in Figure 2, the shape of the valve member (15) is such that any longitudinal movement of the valve member (15) away from the valve seat (16a) would result in fluid flow through the valve lumen.

While claims 20 and 35 recite functional language regarding the operation of the stopper, Applicant respectfully objects to the characterization that such language is “directed to the intended use of the device, and thus does not reflect any structural limitations set forth in the claim.” In determining anticipation, functional language contained within a claim cannot be disregarded. See *Pac-Tec, Inc. v. Amerace Corp.*, 903

F.2d 796, 14 U.S.P.Q.2d 1871 (Fed. Cir. 1990), *cert. denied*, 502 U.S. 808 (1991). Instead, a functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. *See* MPEP § 2173.05(g). In the present case, the language recitation in claims 20 and 35 regarding the operation of the stopper is not merely descriptive of the device's intended use, but instead contains limitations that must be considered in determining anticipation.

Since the *Isaacson* reference fails to disclose or suggest a stopper including a plunger portion configured to move longitudinally within a first lumen portion of an elongated housing in response to fluidic pressure without allowing fluid to flow through the valve lumen, Applicant respectfully asserts that independent claims 20 and 35 are patentable. Moreover, because independent claims 20 and 35 are patentable, dependent claims 21-34 and 36-48 are also patentable for the reasons given above, and since they contain other significant elements to distinguish them from the cited prior art.

In paragraph 5 of the Office Action, the Examiner further rejected claims 20-25, 31, 33, 35-40 and 46 under 35 U.S.C. § 102(e) as being anticipated by *Davis* (U.S. Patent No. 5,713,877). Applicant respectfully traverses this rejection.

As with *Isaacson* described above, Applicant respectfully asserts that the *Davis* reference similarly fails to disclose or suggest a stopper including a plunger portion configured to move longitudinally within a first lumen portion of an elongated housing in response to fluidic pressure without allowing fluid to flow through the valve lumen. The *Davis* reference appears to suggest an elongated drainage valve poppet or rod (50) disposed within a drainage valve cavity (23) of a urinary catheter (35) that can be pulled

away from a valve seat (38) using an external magnetic source (72). As described in *Davis* at col. 5, lines 27-39, and as shown in Figure 2, the poppet or rod (50) has an enlarged, bulbous valve head (52) that permits the poppet or rod (50) to seat properly after use, even when the valve is deformed or bent at a severe angle.

Based on the shape of the poppet or rod (50) described in *Davis*, longitudinal movement of the poppet or rod (50) away from the valve seat (38) would allow fluid to flow through the catheter (35), contrary to that recited in claims 20 and 35. This is readily apparent from the text of *Davis*, which discloses that urine drains through the catheter (35) when the drainage valve poppet (50) is pulled away from the drainage valve seat (38) using the external magnetic source (72).

Since the *Davis* reference fails to disclose each and every limitation contained in claims 20 and 35, Applicant respectfully asserts that the anticipation rejection of these claims is improper. Moreover, because base claims 20 and 35 are patentable, dependent claims 21-34 and 36-48 are also patentable for the reasons given above, and since they contain other significant elements to distinguish them from the cited prior art.

### 35 U.S.C. § 103(a) Rejections

In paragraph 7 of the Office Action, the Examiner rejected claims 26-28 and 41-43 under 35 U.S.C. § 103(a) as being unpatentable over *Isaacson* (U.S. Patent No. 3,812,841). In paragraph 8 of the Office Action, the Examiner further rejected claims 26-28 and 41-43 under 35 U.S.C. § 103(a) as being unpatentable over *Davis* (U.S. Patent No. 5,713,877).

As discussed previously, neither *Isaacson* nor *Davis* disclose or suggest the use of a stopper including a plunger portion configured to move longitudinally within a first

lumen portion of an elongated housing in response to fluidic pressure without allowing fluid to flow through the valve lumen. Instead, both *Isaacson* and *Davis* appear to disclose a different arrangement wherein the valve members permit fluid to flow when moved longitudinally away from the valve seat. Since both references fail to disclose each and every element of claims 20 and 35, Applicant respectfully asserts that dependent claims 26-28 and 41-43 are also patentable over the cited prior art.

#### **Double Patenting Rejections**

In paragraph 9 of the Office Action, the Examiner rejected claims 20-33 and 35-47 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of *Migachyov* (U.S. Patent No. 6,183,413). In paragraph 10 of the Office Action, the Examiner further rejected claims 20-33 and 35-37 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-37 of *Migachyov* (U.S. Patent No. 6,652,448). While acknowledging that the conflicting claims are not identical, the Examiner states that they are not patentably distinct from each other because claims in the present application are broader than the claims in the patent.

Applicant respectfully traverses the Examiner's rejection of claims 20-33 and 35-47 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,183,413, and claims 1-37 of U.S. Patent 6,652,448. An appropriate Terminal Disclaimer is submitted herewith, however, rendering these rejections moot. Applicant does not concede the correctness of the rejection.

**Allowable Subject Matter**

In paragraph 11 of the Office Action, the Examiner indicates that claims 49-62 are allowable. Furthermore, in paragraph 12 of the Office Action, the Examiner states that claims 34 and 48 are objected to as being dependent upon a rejected base claim, but would otherwise be allowable if rewritten in independent form to include all of the limitations of their base claim and any intervening claims.

Applicant respectfully asserts that since amended claim 20 is in condition for allowance, dependent claim 34 is also allowable. Moreover, since amended claim 35 is in condition for allowance, Applicant respectfully asserts that dependent claim 48 is also allowable.

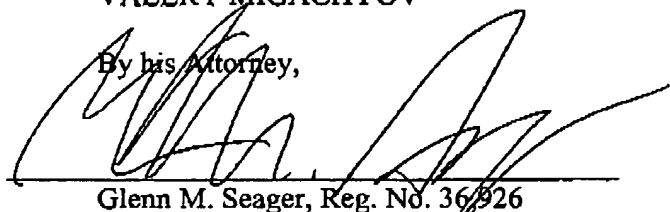
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance, issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By his Attorney,

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